DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 24, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-48

Vinton J. Waldron, President
Waldron Smokehouse Specialties, Inc.
460 East Silverlake Road
Oak Harbor, Washington 98227

WARNING LETTER

Dear Mr. Waldron:

We inspected your firm located at 460 East Silverlake Road, Oak Harbor, Washington, on March 7 and 8, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your hot and cold smoked salmon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (b). Your firm does not have a HACCP plan for cold smoked salmon and smoked salmon pate. In addition, you must follow the plan that you do have, examples of your deviating from your HACCP plan are:

- Your smoked salmon plan critical limit for brining calls for [redacted] pounds of salt to be added to [redacted] pounds of fish. You are not following this part of your plan in that you do not weigh the fish. This observation was brought to your attention during our November 1998 inspection and in our April 26, 1999, letter. During the November 1998 inspection you promised correction to this observation. During the inspection a sample was collected of your smoked salmon. The analytical results showed that your product does not meet the minimum of 3.5% water phase salt (WPS). An average WPS of 2.73% was found with a low of 2.30%.

- Your plan for smoked salmon also states that you will verify that your brining process is adequate by performing quarterly finished product analysis for water phase salt. You have never had this test performed, although you have promised correction to this observation during our November 12, 1998, and our February 3, 2000, inspections.

- Your plan for smoked salmon lists a minimum curing time of [redacted] hours. You are not following this part of your plan since you use different times depending on the variety of salmon being processed.

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6 (b). Your firm did not follow the monitoring procedures of continuous monitoring by recording graph at the smoking and curing critical control point to control the hazard of pathogen growth and *Clostridium botulinum* toxin formation listed in your HACCP plan for smoked salmon in that:

- The recording chart has overlapping cooks for several production runs.
- The recording chart is not signed and dated as having been reviewed.

You must have an adequately trained or qualified individual review HACCP records in order to comply with 21 CFR 123.11 (b). Your plant manager has not had HACCP training although he is reviewing HACCP records including curing logs, smoking/cooking records, and cooler records. In addition, the plant manager is reviewing records that he created. A second HACCP trained individual must do the review.

You must provide a record keeping system that documents the actual values and observations obtained during monitoring. Your salt receiving critical control point log shows the time the brining begins and the anticipated stop time rather than the actual time brining was completed. The recording of a critical limit prior to the actual completion of the step could be considered falsification of records, which is a criminal act under Title 18 U.S.C. This practice also gives no assurance that the critical limit of [redacted] hours of curing has been accomplished and the purpose of this step is to prevent *Clostridium botulinum* toxin formation. This is especially significant in light of our analytical findings of WPS levels well below the 3.5% required.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement